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EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,971	Applicant(s) GATLIN ET AL.	
	Examiner B. Dell Chism	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☒ Claim(s) 1-8,10-12 and 14-21 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is the first action on the merits. Claims 1-21 are pending and are under consideration by the Examiner.

Claim Objections

1. Claims1-8, 10-12 and 14-21 are objected to because of the following informalities: claim 1 requires the insertion of the term "A" prior to combination; claims 2-7 and 14-17 require the term "The" inserted prior to combination; claims 8, 10-12 and 18-21 require amendment to the phrase "[a] combination" wherein the phrase should read "the combination". Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-12 and 20-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as it is unclear what (I) represents in the claim. If (I) is meant to represent a formula, then "formula" should be inserted into the claim. Claim 1 also rejected, as it is unclear what "case" means, i.e., a patient, a single dose, a single formulation.

Claims 1-8 and 10-21 are rejected, as it is not clear what compounds are for simultaneous, separate or sequential use. Also, it is not clear if the claims are drawn to a composition comprising a combination of ingredients or to a combination therapy. Also, it is unclear how a composition comprising a combination can be administered sequentially or separately. It is unclear how the carrier can be administered subsequently to the composition.

Claims 1, 4, 9 and 13-14 are rejected, as it is unclear if an "antidiabetic phenylacetic acid" derivative is different from a plain phenylacetic acid.

Claim 2 is rejected, as it is unclear as to whether the claim is drawn to the same compound as claim1, from which claim 2 depends. Claim 1 recites a combination of nateglinide, either phenylacetic acid or acarbose, and a pharmaceutical carrier. Claim 2 appears to state that the formulation can only be either nateglinide and phenylacetic acid or acarbose or a pharmaceutical. Claim 2 should be amended to properly align with the invention of claim 1.

Claim 3 is rejected for the indefinite recitation of the term "diseases" wherein it is unclear what is encompassed within the metes and bounds of such diseases, i.e., cancer, metabolic diseases or other undefined disorders.

Claim 5 is rejected, because as the claim stands, it is not clear if the combination comprises nateglinide with acarbose or nateglinide with both phenylacetic acid and acarbose.

Claim 6 is rejected, as the metes and bounds of the species of the Markush group are not clear, i.e., "sulphonyl urea derivatives". Furthermore, it is not clear what "where possible" is. Also, it is not clear what is meant by "at least one further antidiabetic phenylacetic acid derivative," wherein it is not clear if it is meant that there is an additional component or if it is a further derived phenylacetic acid.

Claim 8, 12, 18 and 21 are rejected for the indefinite recitation of "cosmetically beneficial loss of body weight" wherein the metes and bounds of the cosmetic benefit are not addressed in the claims or the specification.

Claims 8 and 18 are rejected for the indefinite recitation of the phrase "method of improving the bodily appearance of a mammal" wherein it is unclear as to what the threshold is or would be for measuring "improvement" of the bodily appearance. Furthermore, it is unclear as to what the appearance disorder/disease might be, i.e., it could be a rash, weight, coloration, etc...

Claims 9-10 are rejected for the indefinite recitation of "a quantity, which is jointly therapeutically effective against metabolic disorders." It is not clear if this amount is different from an "effective dose" or a pharmaceutically effective amount."

Claims 11-12 and 20-21 provides for the use of "the combination", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected for the indefinite recitation of the phrase "comprising as active agent nateglinide", wherein it is unclear if the active agent is nateglinide or if there is more than one active agent. The claim should be amended in one of the following forms for clarity; "comprising nateglinide as an active agent [nateglinide]" or "comprising as active agents".

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 3, 11, 13 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent for treating metabolic disorders utilizing a combination or pharmaceutical composition, does not reasonably provide enablement for an agent which prevents or delays the progression of metabolic diseases/disorders. In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. *The breadth of the claims and the nature of the invention*: in the instant case, applicants are claiming a composition that is an agent for "preventing" and "delays the progression of" metabolic diseases. The nature of the invention is of a pharmaceutical for the treatment of a disease, i.e. diabetes. As stated, however, the claim asserts that the composition is capable of preventing or delaying the progression of metabolic disorders/diseases, or to keep from happening.

2. *the state of the prior art*: the state of the art does not teach the absolute prevention or delay the progression of metabolic diseases/disorders, merely that the symptoms of the disease, such as hyperglycemia, hyperinsulinaemia, hyperlipidaemia, stroke, obesity, etc... (specification

page 3,), may be treated. For example, Villhauer (US 6,432,969 B1) only teaches the treatment of the claimed diseases/disorders, not the prevention.

3. *the predictability or lack thereof in the art*: thus, any claim to the prevention and delay of the progression of metabolic diseases, such as diabetes, is highly unpredictable given the current state of the art.

4. *the presence or absence of working examples*: furthermore, applicant states that the invention may be used in the prevention and delay of progression of type 2 diabetes mellitus and associated diseases (specification page 7) but does not provide examples as such. Whereas examples are given for the amelioration of type 2 diabetes mellitus, prevention is not taught.

5. *the amount of direction or guidance present and the quantity of experimentation needed and the level of the skill in the art:* because neither the prior art nor the current application provide sufficient guidance to one of skill in the art as to the prevention or delay of progression of metabolic diseases/disorders such as type 2 diabetes mellitus, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1- 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Villhauer (US 6,432,969 B1).

Villhauer teaches a combination comprising nateglinide, repaglinide and acarbose for the treatment of metabolic conditions and for cosmetics to improve appearance of a mammal, further comprising antidiabetic thiazolidinediones, sulphonyl urea derivatives, metformin and others, for the simultaneous, separate or sequential administration in free form or a pharmaceutical composition, also in a commercial package.

Conclusions

No claims are allowed. Claims 1-8, 10-12 and 14-21 are objected to, and Claims 1-21 are rejected.

Art of Record

Kanstrup *et al.* (US 6,380,398) teaches the combination of nateglinide and acarbose, with antidiabetic thiazolidinediones, sulphonyl urea derivatives and metformin.

Mogensen *et al.* (US 6,569,901) teaches the combination of nateglinide and acarbose, with antidiabetic thiazolidinediones, sulphonyl urea derivatives and metformin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
13 June 2003

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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